

IN THE CLAIMS:

Claims 1 - 4 (PREVIOUSLY CANCELLED)

5. (PREVIOUSLY AMENDED) A lead according to Claim 62, wherein said lead comprises two pairs of electrodes, each of said pairs comprising a sensing electrode and a signal delivery electrode, wherein the sensing electrode of one of said pairs of electrodes is in adjacent axial arrangement with respect to the sensing electrode of the other pair of electrodes.

6. (PREVIOUSLY AMENDED) A lead according to claim 5, wherein each sensing electrode is spaced from the nearest disposed signal delivery electrodes by a distance such as to minimize interference between the signal provided by said sensing electrode and the field provided by said nearest signal delivery electrodes, and such that each said nearest signal delivery electrode provides an electric field that corresponds with said signal provided by the corresponding said sensing electrode.

7. (PREVIOUSLY AMENDED) A lead according to claim 6, wherein the distance is between about 2 mm and about 10 mm.

8. (PREVIOUSLY AMENDED) A lead according to claim 5, wherein each sensing electrode comprises a substantially cylindrical member having an external diameter and having a lumen of a diameter slightly larger than the outer diameter of the distal portion of said lead.

9. (PREVIOUSLY AMENDED) A lead according to claim 8, wherein the cylindrical member comprises a longitudinal length less than the external diameter thereof.

10. (PREVIOUSLY AMENDED) A lead according to claim 9, wherein the external diameter is less than 1.2 mm.

11. (CURRENTLY AMENDED) A lead according to claim 62, wherein each sensing electrode ~~means comprises a sensing electrode~~ is adapted for sensing tissue impedance, pressure, tension or electrical signal.

12. (CURRENTLY AMENDED) A lead according to claim 62, wherein each sensing electrode means comprises a sensing electrode made from a material selected from the group consisting of titanium coated with iridium oxide; titanium coated with titanium nitride; platinum iridium coated with iridium oxide; platinum iridium coated with titanium nitride; platinum iridium coated with sintered platinum; titanium; platinum iridium; pyrolitic carbon; and any other conductive material approved for chronic use in the body.

13. (CURRENTLY AMENDED) A lead according to claim 62, wherein each ~~delivery electrode means comprises a~~ signal delivery electrode is comprised of one or more electrical conducting elements wound in parallel to a spiral coil-like form having an external diameter and having a lumen of a diameter slightly larger than the outer diameter of the distal portion of said lead.

14. (PREVIOUSLY AMENDED) A lead according to claim 13, wherein the external diameter is less than 1.2 mm.

15. (PREVIOUSLY AMENDED) A lead according to claim 13, wherein the spiral coil-like form comprises a longitudinal length substantially greater than the external diameter thereof.

16. (PREVIOUSLY AMENDED) A lead according to claim 15, wherein the longitudinal length is between about 5 mm and about 40 mm.

17. (PREVIOUSLY AMENDED) A lead as claimed in claim 13, wherein the spiral coil-like form comprises an effective external surface area of between about 30 square mm and about 250 square mm.

18. (PREVIOUSLY AMENDED) A lead according to claim 62, wherein each signal delivery electrode means comprises a signal delivery electrode having impedance in the range of between about 50 ohms and about 500 ohms.

19. (CURRENTLY AMENDED) A lead according to claim 62, wherein each ~~delivery electrode means comprises a~~ signal delivery electrode is made from a material selected from the group consisting of titanium coated with iridium oxide; titanium coated with titanium nitride; platinum iridium coated with iridium oxide; platinum iridium coated with titanium nitride; platinum iridium coated with sintered platinum; titanium; platinum iridium; pyrolitic carbon; and any other conductive material approved for chronic use in the body.

20. (PREVIOUSLY AMENDED) A lead as claimed in claim 5, wherein the electrodes are spaced along the lead such as to occupy a lead length of between about 20 mm and about 150 mm.

21. (PREVIOUSLY AMENDED) A lead according to claim 5, wherein each electrode of the two pairs of electrodes comprises at least one suitable conductor having suitable distal connector means and proximal connector means for operatively connecting each corresponding said electrode to said connection means, respectively.

22. (PREVIOUSLY AMENDED) A lead according to claim 21, wherein the electrodes are carried on a terminal support tube comprised on the distal portion of said lead, said terminal support tube comprising a substantially tubular flexible body member comprising a plurality of longitudinal channels, each said channel adapted to accommodate at least one conductor corresponding to one of said electrodes, said channels terminating at a corresponding distal terminal area adapted for accommodating a corresponding distal connector means.

23. (PREVIOUSLY AMENDED) A lead according to claim 22, wherein the distal connector means for each electrode comprises a substantially flat terminal member having an exposed surface substantially larger in area than the transverse cross-sectional area of the corresponding at least one conductor, said distal connector means being adapted for electrically joining thereto the distal end of said corresponding at least one conductor, and said exposed surface adapted for electrically joining thereto a corresponding one of said electrodes.

24. (PREVIOUSLY AMENDED) A lead according to claim 23, wherein a laser weld is used to electrically join each one of the electrodes to the exposed surface of a corresponding one of the distal connector means.

25. (CURRENTLY AMENDED) A lead according to claim 22, wherein each one of the distal connector means ~~comprises a suitable well into which~~ is electrically connected to the distal end of a corresponding one of the at least one conductor ~~is inserted and electrically connected by means of crimping~~ by inserting said distal end of said conductor into a well provided on said distal connector means.

26. (PREVIOUSLY AMENDED) A lead according to claim 23, wherein the flat terminal member is made from titanium.

27. (PREVIOUSLY AMENDED) A lead according to claim 22, wherein the lead comprises a proximal portion joined to the distal portion thereof, wherein said proximal portion comprises a flexible tubular member having a lumen, a proximal portion of the conductors being carried in said lumen in coiled spiral configuration.

28. (PREVIOUSLY AMENDED) A lead according to claim 62, wherein the connection means comprises at least one implantable connector.

29. (PREVIOUSLY AMENDED) A lead according to claim 62, further comprising an ogival intrusion head and a length of suitable tubing, said ogival intrusion head being proximally joined to the distal portion of said lead via said length of suitable tubing.

30. (PREVIOUSLY AMENDED) A lead according to claim 29, wherein the tubing comprises a bend.

31. (CURRENTLY AMENDED) A lead according to claim 30, wherein the bend comprises an angle of between 30° and about 90°; when unstressed.

32. (PREVIOUSLY AMENDED) A lead as claimed in claim 62, further comprising means for introducing and implanting at least the distal portion of said lead within the at least portion of tissue.

Claim 33 (WITHDRAWN) A lead according to claim 1, comprising an external diameter such as to enable said lead to be inserted into a suitable blood vessel having a lumen of diameter less than about 1.5mm.

34 (PREVIOUSLY CANCELLED)

35. (PREVIOUSLY AMENDED) A lead according to claim 62, wherein the parameters include at least one selected from the group consisting of the magnitude, shape duty cycle, phase, frequency and duration of the non-excitatory electric field.

36. (PREVIOUSLY AMENDED) A lead according to claim 62, wherein the control means comprises means for applying to the delivery electrodes a voltage and/or current required for performing an operation chosen from among providing non-excitatory stimuli to the heart or performing pacing or performing defibrillation.

37. (PREVIOUSLY AMENDED) A lead according to claim 62, wherein the control means comprises means for generating a non-excitatory electric field having suitable parameters such as to provide the desired change in the activity of the tissue or part thereof.

38. (CURRENTLY AMENDED) A lead as claimed in claim 62, wherein the location of each electrode relative to the anatomical boundary between the atrium and the ventricle of the heart ~~may be~~ is identified by using said electrode.

39. (CURRENTLY AMENDED) A lead as claimed in claim 62, wherein the location of each electrode relative to the anatomical boundary between different heart chambers ~~may be~~ is identified by using said electrode.

40. (PREVIOUSLY AMENDED) A lead as claimed in claim 62, wherein the control means is characterized in being adapted for either selectively enabling a suitable non-excitatory electric field to be generated by the delivery electrode means such as to provide the desired modification in the activity of the portion of tissue or selectively not generating an electric field, wherein said electric field is either generated or not generated depending on at least one characterizing feature of the signal previously provided by the sensing electrode means.

41. (PREVIOUSLY AMENDED) A lead for modifying the activity of at least a portion of a tissue, the lead comprising:

at least one unitary electrode adapted for sensing activity of said at least portion of a tissue and providing a signal characteristic of said activity, said at least one unitary electrode also being adapted for selectively delivering a suitable non-excitatory electric field to said at least portion of tissue to achieve a desired change;

suitable control means; and

connection means operatively connected to said at least one unitary electrode for enabling said at least one unitary electrode to be operatively connected to said suitable control means.

42. (PREVIOUSLY AMENDED) A lead as claimed in claim 41, wherein the control means is characterized in being adapted for either selectively enabling a suitable non-excitatory electric field to be generated by the at least one unitary electrode such as to provide the desired modification in the activity of the portion of tissue or for selectively not generating an electric field, wherein said electric field is either generated or not generated depending on at least one characterizing feature of said signal previously provided by the same or another said at least one unitary electrode.

43. (PREVIOUSLY AMENDED) A lead for modifying the activity of at least a portion of a tissue, said lead comprising:

at least one sensing electrode adapted for sensing the activity of said at least portion of a tissue and providing a signal characteristic of said activity;

at least one signal delivery electrode adapted for selectively delivering a suitable non-excitatory electric field to said at least portion of tissue to achieve a desired change;

suitable control means; and

connection means operatively connected to said at least one sensing electrode and to said at least one signal delivery electrode for enabling said at least one sensing electrode and said at least one signal delivery electrode, respectively, to be operatively connected to said suitable control means.

44. (PREVIOUSLY AMENDED) A lead as claimed in claim 43, wherein the control means is characterized in being adapted for either selectively enabling a suitable non-excitatory electric field to be generated by said at least one signal delivery electrode such as to provide the desired modification in the activity of the portion of tissue or for selectively not generating an electric field, wherein said electric field is either generated or not generated depending on at least one characterizing feature of the signal previously provided by the at least one sensing electrode.

45. (PREVIOUSLY AMENDED) A lead according to any proceeding claim, wherein the tissue to be modified by said lead is tissue of a human heart or part thereof.

46. (WITHDRAWN) A lead according to claim 45, optionally for performing pacing of said heart.

47. (WITHDRAWN) A lead according to claim 45, optionally for performing defibrillation of said heart.

48. (WITHDRAWN) A lead according to any one of claims 1 to 44 and 46 to 47, wherein said lead is implanted into a vessel or body cavity using any suitable implantation method.

49. (CANCELLED)



50. (WITHDRAWN) A method for applying non-excitatory stimuli to the heart and optionally performing pacing and defibrillation thereof, comprising providing a lead as claimed in any one of claims 1 to 44 and 46 to 47, and positioning said distal portion of the lead within a blood vessel of said heart or portion thereof.

51. (WITHDRAWN) A method for applying non-excitatory stimuli to said tissue, comprising providing a lead as claimed in any one of claims 1 to 44 and 46 to 47, and positioning said distal portion of the lead within a blood vessel of said \ tissue or portion thereof.

52. (WITHDRAWN) A method according to claim 51, wherein said tissue is a body organ.

53. (WITHDRAWN) A method according to claim 51, wherein said tissue is a body cavity.

54. (WITHDRAWN) A method according to claim 53, wherein said body cavity is the heart.

55. (WITHDRAWN) A method according to claim 53, wherein said body cavity is a blood vessel.

56. (WITHDRAWN) A method according to claim 53, wherein said body cavity is selected from among the urinary bladder, the gastro-intestinal system, the uterus and the larynx.

57. (WITHDRAWN) A method for applying non-excitatory stimuli to the heart and optionally performing pacing and defibrillation thereof, comprising providing a lead as claimed in any one of claims 1 to 44 and 46 to 47, and positioning said distal portion of the lead on the epicardium of said heart.

58. (WITHDRAWN) A method for applying non-excitatory stimuli to said tissue, comprising providing a lead as claimed in any one of claims 1 to 44 and 46 to 47, and positioning said distal portion of the lead on the epicardium of said heart.

59. (WITHDRAWN) A method according to claim 58, wherein said tissue is the cervix.

60. (WITHDRAWN) A method according to claim 58, wherein said tissue is the uterus.

61. (WITHDRAWN) A method according to claim 58, wherein said tissue is the urinary bladder.

62. (CURRENTLY AMENDED) A lead for modifying the activity of at least a portion of a tissue, said lead connectable to suitable control means and comprising:

a proximal portion and a distal portion;

one or more ~~sensing electrodes~~ electrode means adapted for sensing activity of said at least portion of a tissue and providing a signal characteristic of said activity;

one or more ~~delivery electrode means adapted to be capable of~~ electrodes adapted for selectively delivering a ~~suitable~~ non-excitatory electric field to said at least portion of tissue to achieve a desired ~~change~~ modification in the activity of at least a local portion of a said portion of a tissue; and ~~wherein one or more of said delivery electrode means may comprise a unitary electrode, in which the delivery electrode means have been adapted to additionally function as one or more of said sensing electrode means;~~

~~suitable control means; and~~

connection means ~~operatively connected~~ for operatively connecting to said electrode means for enabling said electrodes electrode means to be operatively connected to said control means;

wherein said lead is adapted to withstand chronic non-excitatory electric signal delivery; said sensing electrodes adapted for sensing ~~electrode means~~ are distributed along at least part of the length of said lead such that each of said ~~delivery electrodes adapted for delivery~~ electrode means has at least one of said sensing electrodes adapted for sensing ~~electrode means~~ associated with it, said associated electrodes adapted for sensing and delivery ~~electrode means~~ being ~~either~~ located in close proximity to one another ~~or comprising a unitary electrode~~; and

said control means comprise means for receiving signals from each of said sensing electrodes adapted for sensing ~~electrode means~~, determining from said received signals the characteristics of the activity sensed by each of said electrodes adapted for sensing ~~electrode means~~, determining on the basis of said characteristics the individual parameters and the sequencing of the non-excitatory electric field to be provided by each of said electrodes adapted for delivery ~~electrode means~~ associated with each of said electrodes adapted for sensing ~~electrode means~~, and supplying the appropriate electric current and/or potential to each of said electrodes adapted for delivery ~~electrode means~~ in order to produce said non-excitatory electric field, having the necessary magnitude, shape, duty cycle, phase, frequency, and duration suitable to obtain said modification.

63. (CURRENTLY AMENDED) A lead according to claim 6, wherein the distance is about ~~5mm~~ 5 mm.

64. (CURRENTLY AMENDED) A lead according to claim 15, wherein the longitudinal length is about ~~20mm~~ 20 mm.

65. (PREVIOUSLY PRESENTED) A lead according to claim 28, wherein the at least one implantable connector is an ISI connector.

66. (PREVIOUSLY PRESENTED) A lead according to claim 30, wherein the bend comprises an angle of about 45° when unstressed.

67. (CURRENTLY AMENDED) A lead according to claim 62, comprising an external diameter such as to enable said to be introduced to its implantation site by passing through a lumen of diameter less than ~~1.5mm~~ 1.5 mm.

68. (NEW) A lead according to claim 62, comprising an external diameter such as to enable said lead to be introduced through the coronary sinus.

69. (NEW) A lead according to claim 62, wherein one or more of the electrodes adapted for delivery and their associated one or more electrodes adapted for sensing may comprise a unitary electrode, said unitary electrode alternately used to sense activity of at least a portion of a tissue and provide a signal characteristic of said activity and to deliver a non-excitatory electric field to said at least portion of tissue to achieve a desired modification in the activity of said least a portion of a tissue.